UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA and the STATE OF TENNESSEE ex rel. JEFFREY H. LIEBMAN and DAVID M. STERN, M.D. **Plaintiff,** **v.** **METHODIST LE BONHEUR HEALTHCARE, METHODIST HEALTHCARE-MEMPHIS HOSPITALS,** **Defendants.**	**Case No. 3:17-CV-00902** **District Judge William L. Campbell, Jr.** **Magistrate Judge Barbara D. Holmes**

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

After nearly six years of government investigation and litigation by relators and the government, there is no proof that Methodist Le Bonheur Healthcare or Methodist Healthcare-Memphis Hospitals (collectively "Methodist") violated the Anti-Kickback Statute ("AKS") or the False Claims Act ("FCA"), and Methodist is entitled to summary judgment on all claims.

For years, cancer care in Memphis was plagued by fragmentation and a lack of coordination among providers, resulting in poor outcomes and widening health disparities. In 2011, Methodist and Memphis' premier private oncology practice, The West Clinic ("West"), entered into an affiliation to improve cancer care and to become an integrated and multidisciplinary cancer center.

The parties devoted significant efforts and resources to ensure that the affiliation complied with applicable laws and regulations. Prior to executing contracts, the parties engaged national law firms with recognized healthcare expertise to draft the agreements based on similar hospital-physician integrations around the country. Methodist also engaged a national consulting firm to structure the management agreement based on its experience setting up similar arrangements. The parties set the compensation according to amounts that independent valuation firms determined would be fair market value for the services provided.

The affiliation, known as West Cancer Center, operated from 2012 to 2018 and was a remarkable success for Memphis and the region. It integrated previously fragmented care; recruited nationally-known cancer specialists to Memphis; received more than a dozen certifications and accreditations from national cancer organizations; and, most importantly, improved cancer care, reduced disparity gaps, and extended patient lives—regardless of patients' ability to pay.

Yet, the government claims that West Cancer Center was a fraud scheme and that *all claims* billed by Methodist over the entire time period are false. The government does not contest that

West Cancer Center integrated care, created new programs, or recruited specialists, or that cancer care improved in Memphis. Also, the government does not, and cannot, contest that Methodist paid fair market value to West for services it provided. Instead, the government nit-picks certain contractual provisions, argues that Methodist should have divined alleged errors in certain fair market value opinions, and asserts that some fair market value opinions were inconsistent with the parties' agreements. This is not the stuff of criminal bribes and kickbacks. In a seminal decision issued weeks ago, the Sixth Circuit rejected a similarly broad over-application of the AKS, holding that a "faithful interpretation" of the elements of the AKS is meant "to target genuine corruption." *U.S. ex rel. Martin v. Hathaway*, 2023 WL 2661358 at *9 (6th Cir. Mar. 28, 2023). Even after six years, the government's case fails at every level, and there is no proof that Methodist violated the AKS, let alone that the West Cancer Center affiliation amounted to "genuine corruption."

Summary judgment should be granted for three reasons. *First*, there is no evidence – as required by *Martin* – that referrals from West physicians "resulted from" inappropriate payments. *Second*, there is no evidence that Methodist provided "remuneration" to West as defined by the AKS because the government can identify no evidence that Methodist's payments to West exceeded fair market value. *Third*, there is no evidence that Methodist acted with the required scienter. To the contrary, Methodist acted in accordance with a reasonable interpretation of the AKS that paying fair market value for services rendered was appropriate, and there is no evidence to show that Methodist knew its conduct was wrongful.

Unsupported speculation that Methodist *must have* somehow made inflated payments to West doctors and that those payments *must have* somehow caused West doctors to refer some unidentified patients to Methodist hospitals cannot establish an FCA violation, and this case should be dismissed.

BACKGROUND

I. Factual Background

Methodist is a nonprofit, faith-based healthcare system that has been serving the greater Memphis area for over 100 years. (SUMF ¶ 6.)[1] As of 2010, Methodist operated numerous hospitals that provided care to patients from across the Mid-South (*Id.* ¶ 8), and West was the premier oncology practice in Memphis with nearly thirty doctors in various specialties. (*Id.* ¶ 13.)

Cancer care in Memphis at that time was disjointed, fragmented, and suffered from a lack of collaboration among providers. (*Id*. ¶ 1.) Patients often bounced between different physicians and institutions for their care or had to travel to other cities to receive specialized treatment not offered in Memphis. (*Id*. ¶ 2.) "Patient care and outcomes suffered as a result." (*Id.* ¶ 5.)

To address these issues, West issued a Request for Proposal ("RFP") to multiple Memphis-area health systems, including Methodist, proposing to enter into an affiliation to "promote standardization of services, and improve the quality, efficiency and operations of the Hospital's medical oncology [] services, potentially access all of the Hospital's sites of care." (*Id.* ¶ 18.) The affiliation structure proposed by West had been used by others in the healthcare industry as a way to integrate oncology groups and hospitals. (*Id.* ¶ 20.)

West proposed that: (1) West's clinic sites ("Cancer Center Sites") convert to provider-based outpatient departments of a hospital, (2) the hospital enter into a professional services agreement with West for clinical services, (3) the hospital lease West's employees to staff the service line, and (4) West be paid to co-manage the hospital's oncology service line. (*Id.* ¶ 19.) West wanted to partner with Methodist due to its nonprofit status and focus on providing

[1] In accordance with Fed. R. Civ. P. 56 and Local Rule 56.01, Methodist is filing herewith a Statement of Undisputed Material Facts in support of its Motion for Summary Judgment ("SUMF").

community care, which West believed would provide it additional opportunities to address treatment disparities. (*Id.* ¶ 22.)

Methodist shared West's vision for bringing integrated cancer care to Memphis and saw partnering as a way to bring the breadth and quality of West's services to the patient population Methodist served. (*Id.* ¶ 25.) Like West, Methodist wanted not only to provide the best cancer care not just in Memphis but to develop a comprehensive cancer center that could become a regional destination for state-of-the-art cancer care. (*Id.*) Methodist responded to West's RFP, and West ultimately selected Methodist as its future affiliation partner. (*Id.* ¶¶ 26–27.)

West engaged the law firm of Foley & Lardner to negotiate and structure the affiliation with Methodist based on Foley's experience structuring similar arrangements, in particular a cancer center affiliation for the University of Pittsburgh Medical Center. (*Id.*¶ 21.) For its part, Methodist engaged Jones Day, which also had healthcare expertise and experience in developing arrangements of the type West proposed. (*Id.*¶ 28.)

The parties agreed that West would provide clinical services to Methodist patients through a Professional Services Arrangement ("PSA") that compensated West on a "wRVU" basis[2] for work performed. (*Id.* ¶ 63.) Methodist engaged ECG Management Consultants ("ECG") to work in coordination with Jones Day to determine the fair market value of the clinical services West would provide. (*Id.* ¶ 65.) The parties agreed that Methodist would pay West the amount of compensation ECG determined to be fair market value. (*Id.* ¶ 66.) The wRVU rates from ECG's fair market value opinion were incorporated into the PSA, and throughout the affiliation, Methodist

[2] A work relative value unit ("wRVU") is a standard unit of measurement of the time, skill, training, and intensity required of a physician to provide a given service. (Compl. ¶ 131.)

paid West using the rates ECG determined to be fair market value. (*Id.* ¶ 67.) Methodist, however, was not privy to how West in turn compensated its own physicians. (*Id.* ¶ 69.)

West managed Methodist's oncology service line pursuant to a Management Services Agreement ("MSA"). (*Id.* ¶ 70.) Methodist engaged PricewaterhouseCoopers ("PwC") to develop the specific management services in the MSA, as PwC had significant experience constructing similar affiliation transactions across the country. (*Id.* ¶¶ 30–31.) Methodist and West believed it was critical to engage an experienced consulting firm to ensure the affiliation was created by experts who knew the best way to "actually reach and build an integrated oncology program between a community oncology clinic and a hospital-based oncology program." (*Id.* ¶ 32.) Jones Day engaged HealthCare Appraisers, Inc. ("HAI") to value the management services PwC developed. (*Id.* ¶ 71.) Methodist paid West the amount of compensation HAI determined to be fair market value for the management services. (*Id*. ¶¶ 72, 132–133.)

Beyond the initial valuations, independent third-party firms revalued the PSA and MSA throughout the course of the affiliation to ensure continuing fair market value compensation for West's services. (*Id.* ¶ 76.) And, during this litigation, Methodist engaged an expert to conduct a retrospective analysis of the management and professional fees, which confirmed that they were consistent with fair market value. (*Id.* ¶ 46.) That analysis confirmed that West actually *earned less* under the PSA than it had been earning in independent practice prior to the affiliation. (*Id.* ¶ 47.) It also confirmed that similar management arrangements resulted in management fees of between 2.28% and 4.42% of revenue, while West earned between 1.58% and 2.28% during the affiliation. (*Id.* ¶ 49.)

Although West physicians provided clinical and management services to Methodist's adult oncology service line, they uniformly testified and it is undisputed that they were not required to

send their patients to Methodist. (*Id.* ¶ 173.) It is also undisputed that the physicians' referral decisions remained subject to their independent clinical judgment based on their patients' best interests. (*Id.* ¶¶ 178–79.) Before the affiliation, West physicians were already sending their patients to Methodist. (*Id.* ¶ 177.) During the affiliation, they kept their privileges at other hospitals and did not remove their patients from other systems when care at those systems was appropriate. (*Id.* ¶¶ 175–76.) And, after the affiliation ended, they have continued to send their patients to Methodist when they believe Methodist can provide the best care. (*Id.* ¶¶ 178–79.)

As part of the affiliation, Methodist acquired the assets of West's practice located within the Methodist service area to use as part of Methodist's adult oncology service line. (*Id.* ¶ 50.) Methodist engaged Horne, LLP to determine the fair market value of West's fixed assets, leasehold improvements, and inventory. (*Id.* ¶ 51.) The parties agreed that Methodist would pay West the compensation amount that Horne determined to be fair market value for those assets. (*Id.*) After the transfer of assets, West's former clinic locations became outpatient locations of Methodist hospitals. (*Id.* ¶ 57.)

Per the affiliation structure, many of West's clinical employees, including its nurses at the Cancer Center Sites, became Methodist employees. (*Id.* ¶ 54.) West leased other non-physician employees to Methodist on a pass-through basis under a Leased Employee and Administrative Services Agreement ("LEA"). (*Id* ¶ 55.) Because some leased employees spent a portion of their time working for West's non-affiliation business that had not been acquired by Methodist, the parties created and documented an overhead allocation and repayment process for West to reimburse Methodist for time and expense associated with non-affiliation work. (*Id.* ¶¶ 59–60.) Over the course of the affiliation, West paid Methodist approximately $8.2 million for those dual-use assets and leased employees through this true-up process. (*Id.* ¶ 62.)

It is undisputed that the parties' affiliation, which became known as the "West Cancer Center," drastically improved cancer care both at Methodist and in Memphis. (*Id.* ¶¶ 9, 78, 100, 110, 153.) The West physicians assumed leadership roles across the Methodist service line, where they standardized care, developed multidisciplinary treatment protocols, hosted multidisciplinary care conferences, trained Methodist's physicians and nurses, recommended new equipment and facilities, and helped the cancer center achieve more than a dozen rigorous quality certifications from national cancer organizations. (*Id.* ¶¶ 79–131, 153–172.) Methodist's leadership stayed in constant coordination with West, meeting regularly to discuss the service line's day-to-day operations as well as larger strategic initiatives, recruiting efforts, and community impact of cancer services. (*Id.* ¶ 130.) Among other numerous accomplishments, the parties increased clinical trials and early detection screening, decreased hospital and emergency room admissions, reduced surgical infections, increased patient and associate satisfaction scores, and developed new patient-navigation, genetics, survivorship, and weight loss programs. (*Id.* ¶ 159.) Most importantly, they increased survival outcomes for the cancer center's patients, regardless of their ability to pay. (*Id.*)

In 2018, upon the affiliation agreements' expiration, West decided to pursue other business ventures, and West and Methodist ended their affiliation pursuant to the terms of an Unwind Agreement negotiated before the deal began. (*Id.* ¶¶ 18, 181.) West re-assumed the leases of the Cancer Center Sites. (*Id.* ¶ 187.) West also purchased from Methodist the new Cancer Center location on Wolf River Boulevard that opened during the affiliation for $51 million, as well as other equipment, furniture, and assets for an additional $16 million. (*Id.*) In keeping with the parties' practice throughout the affiliation, these prices were determined according to independent fair market value opinions. (*Id.* ¶ 188.) Methodist and West resumed their status as independent organizations serving cancer patients with West physicians maintaining credentials on Methodist's

medical staff and referring patients to Methodist on an as-needed basis. (*Id.* ¶ 190.)

II. Procedural Background

Relator Jeff Liebman filed this *qui tam* lawsuit under seal on May 30, 2017. (Dkt. No. 1.) The government declined to intervene after two years of investigation. (Dkt. Nos. 44, 45.) Liebman added David Stern as a co-relator and the case was unsealed. (Dkt. Nos. 59, 61.)[3]

Over the years, Methodist filed motions to dismiss different iterations of Relators' complaint. (Dkt. Nos. 79, 174.) The filing of subsequent versions of the complaint and the government's delayed intervention mooted these motions, and the merits were not considered by the Court. As a result, this motion for summary judgment will be the first time the Court has considered the sufficiency of the evidence and the merit of the allegations against Methodist.

In January 2021, with the government's consent, Relators settled with West in exchange for West paying $1.3 million to the government, paying $1.3 million to Relators' counsel, and agreeing to enter into a "cooperation agreement" to provide documents and information to Relators for the continued prosecution of this case against Methodist. (Dkt. No. 145-2.)

In October 2021, after the case had been pending for four years, and only six weeks prior

[3] Relator Liebman served as CEO of one of Methodist's hospitals from 2014 to 2017. (Compl. ¶ 19; Answer ¶ 19.) Liebman had received a final written warning about his employment at Methodist in January 2017, and he filed this lawsuit a few months later. (SUMF ¶ 191.) Liebman conceded he did not know how West physicians were compensated by Methodist or how any physician's compensation changed during the affiliation, nor did he have any personal knowledge about the unwinding of the affiliation. (*Id.* ¶ 192.)

Relator Stern was Executive Dean of the University of Tennessee Health Science Center ("UTHSC"), with which Methodist has been affiliated. (Compl. ¶¶ 20, 82; Answer ¶¶ 20, 82.) During the affiliation, he served as a UTHSC representative on the strategic council for the West Cancer Center. (Compl. ¶ 20; Answer ¶ 20.) He was removed from his role as Dean in 2017. (SUMF ¶ 194.) He was subsequently placed on administrative leave and then terminated from another leadership position at UTHSC soon after. (*Id.*) Stern retired from UTHSC in 2019. (*Id.* .) Stern conceded he never saw the MSA, and likewise had no personal knowledge of the unwinding of the affiliation. (*Id.* ¶ 195.)

to the close of fact discovery, the United States moved to intervene. (Dkt. No. 193.) Methodist opposed the late intervention as highly prejudicial to Methodist given the length of the case's pendency. (Dkt. No. 195.) In March 2022, the Court denied the government's motion to intervene as to West but allowed intervention as to Methodist. (Dkt. Nos. 231–32.)

The government's Complaint in Intervention—the fifth version of a complaint filed—is the operative complaint. (Dkt. No. 235 ("Compl.").) Methodist answered and denied liability. (Dkt. No. 242.) Based on the government's representation to the Court when seeking intervention that it was up to speed on the case and would narrow the scope of the case moving forward, the parties agreed to complete the remaining discovery by September 23, 2022. (Dkt. No. 252.)

After the close of fact discovery, the Magistrate Judge found that the government had not followed through on its "representations and assurances to the Court that this would not become effectively a new lawsuit" and that "this has, in fact, morphed into a new lawsuit with new voluminous and sometimes unfounded discovery disputes, and we're going to put an end to that." (Dkt. No. 299 at 7–8.) The Magistrate Judge further (1) found that "the government has not demonstrated diligence in attempting to comply with the September 23rd, 2022 [discovery] deadline," (2) refused to allow the government additional fact depositions, (3) deemed the government to have admitted numerous facts, and (4) closed fact discovery effective September 23, 2022. (*Id.* at 21.)

III. Government's Complaint in Intervention and Contentions Regarding Remuneration

The government alleges that Methodist violated the AKS and, therefore, the FCA. (Compl. ¶ 1.)[4] "The AKS … is a federal criminal statute that prohibits the knowing and willful

[4] Prior to government intervention, Relators had alleged that the West Cancer Center affiliation also violated the Stark Law, which is a civil statute prohibiting certain financial arrangements between hospitals and physicians who refer patients to those hospitals. (*See, e.g.*, Dkt. No. 59.)

payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs." (*Id*. ¶ 27.) According to the government, a "person violates the FCA when that person knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS." (*Id.* ¶ 37.) The government contends that Methodist falsely certified on claims and cost reports that it acted in compliance with the AKS when, in fact, it violated the AKS. (*See id.* ¶¶ 43–75.)

The government alleges that "the multi-agreement structure" between Methodist and West "was a vehicle for kickbacks" that "was designed so that physicians and hospitals could align in a manner that would avoid regulatory issues." (*Id*. at p.38 § II; ¶ 203.) The government alleges that under the MSA, "[k]ickbacks for the revenues Methodist generated from the West referrals, however, were disguised as payments Methodist made during the deal, and expressly for certain services that were supposed to be—but were not—provided under the MSA." (*Id*. ¶ 5; *see also id.* ¶¶ 204–84).) The government alleges that "the conduct of Methodist and West show that those agreements were largely meaningless paper" and that West continued "running the business of West" for its own, independent benefit. (*Id.* ¶¶ 286, 305; *see generally id.* ¶¶ 285–307.)

How exactly Methodist violated the AKS and what exactly constituted the allegedly improper remuneration to West has been a moving target during the litigation. To pin down what specific conduct it was supposed to defend, Methodist issued an interrogatory asking the government to identify all unlawful remuneration that it contended Methodist offered or paid. (SUMF ¶ 198 (Interrogatory No. 2).) In response, the government ultimately[5] identified the four

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The government's complaint dropped all allegations that any arrangement violated the Stark Law. The only remaining claims are whether Methodist's financial arrangements violated the AKS.

[5] The government originally answered this interrogatory on July 25, 2022, and then amended its answers on December 19, 2022, January 25, 2023, and February 10, 2023. (SUMF ¶¶ 197–99.)

following alleged acts:

1. "Methodist allowed West to continue to operate itself out of the same locations that it sold under the Asset Purchase Agreement ('APA') or that Methodist otherwise purchased during the relationship without any documented payment for rent or overhead." (SUMF ¶ 199 at 7.)

2. Methodist "paid the West oncologists approximately $60 million in excess of their professional collections over the time period of 2012-2018." (*Id*.)

3. Prior "to the deal, West provided much of same base management services for the business of West without compensation." (*Id.*)

4. Methodist "paid West under the LEA for much of the work West purportedly was doing under the MSA." (*Id.* at 8.)

None of this conduct, however, amounts to unlawful remuneration under the AKS, and Methodist is entitled to summary judgment as to all claims.[6]

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). At the outset, the moving party has the burden to inform the Court of the basis for its motion and to identify portions of the record that demonstrate the absence of a genuine dispute over material facts. *See Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003). The moving party may satisfy this burden by presenting affirmative evidence that negates an element of the non-moving party's claim or by demonstrating an absence of evidence to support the nonmoving party's case. *Id*.

Following the close of fact discovery, the government sought to add new forms of remuneration not previously raised in its complaint or during fact discovery. (*See id*. ¶ 199.) The interrogatory answers served on February 10, 2023 are the operative answers. (*Id.*)

[6] The Complaint in Intervention brings four causes of action under various provisions of the FCA. Methodist seeks summary judgment as to all causes of action for the reasons set forth herein.

The Court must view the facts in the light most favorable for the nonmoving party and draw all reasonable inferences in its favor. *See Bible Believers v. Wayne Cty., Mich*., 805 F.3d 228, 242 (6th Cir. 2015). The Court does not weigh the evidence, judge the credibility of witnesses, or determine the truth of the matter. *See Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 249 (1986). Rather, the Court determines whether the non-moving party has come forward with sufficient evidence to make the issue of material fact a proper jury question. *Id*.

Of course, the mere scintilla of evidence in support of the nonmoving party's position is insufficient to defeat summary judgment; instead, there must be evidence from which the jury could reasonably find for the nonmoving party. *See Rodgers*, 344 F.3d at 595. Likewise, "speculation is insufficient to establish a genuine issue of material fact." *Goodman v. J.P. Morgan Inv. Mgmt.*, 954 F.3d 852, 865 (6th Cir. 2020); *Jordan v. Howard*, 987 F.3d 537, 545 (6th Cir. 2020). Indeed, speculation about motivation is not evidence at all and is insufficient to create a triable issue of fact. *See McQueen v. Barr*, 782 F. App'x 459, 466 n.3 (6th Cir. 2019); *Tyson v. Sterling Rental, Inc.*, 836 F.3d 571, 583 (6th Cir. 2016). Finally, "a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial" and "mandates the entry of summary judgment for the moving party." *Celotex Corp. v Catrett,* 477 U.S. 317, 322–23 (1986).

ARGUMENT

The FCA imposes civil liability for "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim [to the government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Among other types of false claims, the FCA reaches claims for "items or services resulting from" an AKS violation, which prohibits medical providers from making referrals "in return for" illegal "remuneration." 42 U.S.C. § 1320a-7b(b); *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 2023 WL 2661358 (6th Cir. 2023).

The government alleges Methodist violated the FCA by falsely certifying AKS compliance on claims and cost reports when its relationship with West allegedly amounted to an AKS violation. To establish an FCA violation, the government must prove that (1) the defendant knowingly [scienter]; (2) presented or caused to be presented [causation]; (3) a false claim [falsity]; and (4) such falsity was material to the government's payment decision [materiality]. 31 U.S.C. § 3729(a)(1)(A); *United States v. Wal-Mart Stores East, LP*, 858 F. App'x 876, 878 (6th Cir. 2021). Methodist is entitled to summary judgment because the government has not proven: (1) causation (that any claim resulted from an AKS violation); (2) falsity (that Methodist violated the AKS); or (3) scienter (that Methodist knowingly and willfully violated the AKS or knowingly submitted false claims).

First, the government has not established causation because the government only speculates, with no evidence, that any Medicare referral "*resulted from*" unlawful remuneration paid to a West physician. *See Martin,* 2023 WL 2661358, at *7. The government fails not only to tie any alleged referral to any unlawful remuneration paid to a West physician, but also to identify any evidence that West mandated its physicians to refer patients to Methodist. To the contrary, the undisputed evidence, as West physicians uniformly testified, is that no such mandate existed. *Cf. Martin,* 2023 WL 2661358, at *7-9 (affirming FCA/AKS dismissal at pleading stage when plaintiffs failed to identify any specific referrals, on a physician-by-physician, claim-by-claim basis, that would not have occurred but-for the unlawful remuneration). The government would not even satisfy the FCA's pleading standard for alleging causation, let alone survive summary judgment, which requires "concrete evidence from which a reasonable juror could return a verdict" in its favor. *Anderson*, 477 U.S. at 256; *Martin*, 2023 WL 2661358, at *7-8.

Second, the government cannot establish falsity because Methodist did not pay unlawful

"remuneration" to West. Courts have held that the term "remuneration" used in the AKS requires a payment to be other than fair market value. *See Bingham v. HCA, Inc.*, 783 F. App'x 868, 873-75 (11th Cir. 2019)*; Miller v. Abbott Labs*, 648 F. App'x 555, 561 (6th Cir. 2016); *Jones-McNamara v. Holzer Health Sys.,* 630 F. App'x 394, 400 (6th Cir. 2015). In this case, because the payments at issue were fair market value as determined by qualified industry experts, there was no unlawful remuneration and, consequently, no AKS violation. Additionally, the government cannot point to any evidence that any claim for services submitted to any federal healthcare program was objectively false.

Third, there is no evidence that Methodist "knowingly and willfully" violated the AKS and, as a result, violated the FCA. Methodist possessed an objectively reasonable interpretation of the law that no AKS violation existed if each component of the transaction was paid at fair market value. And, no official governmental guidance existed to warn Methodist away from its objectively reasonable interpretation. Therefore, Methodist could not have knowingly violated the law. *See, e.g., U.S. ex rel. Olhausen v. Arriva Med., LLC*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022).

I. There Is No Proof That Any Referral Resulted from a Violation of the AKS.

The government cannot survive summary judgment on its AKS claim because there is no proof that any allegedly false claim resulted from a violation of the AKS. The AKS provides that "a claim that includes items or services *resulting from* a violation [of the AKS] constitutes *a false or fraudulent claim* for purposes of the [FCA]." 42 U.S.C. § 1320a-7b(b). Put differently, "[w]hen it comes to violations of the [AKS], only submitted claims resulting from the violation are covered by the [FCA]." *Martin*, 2023 WL 2661358, at *7 (internal citation omitted); *see also U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828, 834–35 (8th Cir. 2022). The government cannot establish—through concrete, admissible evidence—that any claim would not be have been submitted to a

government healthcare program "but for" Methodist's payment of unlawful remuneration. *Id.*[7]

As the Sixth Circuit held just weeks ago in *Martin*, this requires a physician-by-physician, claim-by-claim analysis showing that unlawful remuneration caused the physician-referrals at issue. The Sixth Circuit's analysis is dispositive and fatal to the government's claims in this case. In *Martin*, the relator alleged that a hospital's agreement with a physician practice not to employ the relator (who would have been a competing ophthalmologist)—in return for a general commitment from the practice to continue sending surgery referrals to the hospital—violated the AKS and resulted in the submission of false claims. *Martin*, 2023 WL 2661358, at *1. The Sixth Circuit held that the relator's view of both "remuneration" and "causation" under the AKS was far too broad, warning that "reading causation too loosely or remuneration too broadly appear as opposite sides of the same problem. Much of the workaday practice of medicine might fall within an expansive interpretation of the [AKS]. Worse still, the statute does little to protect doctors of good intent, sweeping the vice-ridden and virtuous alike." *Id.* at *8.

On causation, the Sixth Circuit analyzed each of the claims the relator alleged were the result of an AKS violation. For surgeries performed at the hospital, the Sixth Circuit pointed to the lack of allegations that any physician was ordered or mandated by defendants to perform the surgeries there. *Id.* at *7. For claims submitted by the physician practice that came from hospital referrals, the Sixth Circuit found that "individual physicians [at the hospital] ultimately decided to

[7] Given the FCA's title and statutory language, "[i]t seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim." *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys.*, 637 F.3d 1047, 1055 (9th Cir. 2011). The FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *U.S. ex rel. Owsley v. Fazzi Assocs.*, 16 F.4th 192, 196 (6th Cir. 2021). Thus, the government must link the elements of liability to each claim it contends violates the FCA. 31 U.S.C. § 3731(d); *see generally U.S. ex rel. Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006) (pointing out that the "fraudulent claim is the *sine qua non* of [an FCA] violation" and that the alleged falsity of a claim cannot be based upon "speculation") (internal quotation and citations omitted).

whom they would refer patients," and because the relator "failed to allege that [the hospital] could control or direct the referral decisions of its physicians, their independent choices doom the chain of causation there, too." *Id.* at *8. Finally, for the one surgery the relator identified that the defendant performed seven months after the hospital agreed not to hire the relator, the Sixth Circuit observed that not only had the relator failed to identify any exchange of value "to anchor the scheme in time or place," but also that "[t]emporal proximity by itself does not show causation, and seven months would create few inferences of cause and effect anyway." *Id.* (citation omitted).

What the government offers here amounts to even less and would not survive a motion to dismiss, let alone summary judgment. Ignoring every link in the chain of causation, the Court would have to accept the bald assumption that because the affiliation agreements between West and Methodist ran from 2012–2018, any claim submitted by Methodist or West as part of that affiliation *must have* been the result of some criminal kickback. But, West does not treat or refer patients—its physicians do. The government would ask the Court to assume that because West entered into an affiliation with Methodist, then every patient-referral decision by every physician associated with West for more than seven years was the direct result of a kickback from Methodist. At summary judgment, this is a bridge too far.

Despite knowing its burden of proof, the government offers no evidence regarding which, if any, of the *hundreds of thousands* of claims submitted during the affiliation *resulted from* unlawful remuneration paid to the physician who referred those services. During discovery, Methodist asked the government to identify the claims it alleges to be false, including the basis on which the government contends the claims are false. (SUMF ¶ 200.) The government offered this response:

> Under the Anti-Kickback Statute ('AKS'), damages are measured by the false claims are [sic] the claims Defendants submitted or caused to be submitted to

> Medicare that were obtained through Methodist's unlawful relationship with West. The time period the claims were submitted commences January 1, 2012 through December 31, 2018…***Given the number of claims at issue, the United States refers to the claims data produced in this action***…

(*Id.*) (emphasis added). Methodist then sought Rule 30(b)(6) deposition testimony from the United States regarding "[f]or each CLAIM that YOU identify as false, the factual basis and methodology for YOUR determination that the CLAIM *resulted from* any alleged kickback." (*Id.* ¶ 201.) (emphasis added). The government designated Michael Petron, an outside consultant who is not an employee of the government, as its 30(b)(6) representative. (*Id*.) Mr. Petron testified that he was provided a dataset that included claims associated with 86 West physicians, and he calculated the total amount of reimbursed claims submitted by those physicians. (*Id*. ¶ 202.)

In remarkable testimony, the United States' own designated representative could not explain (1) how the list was compiled; (2) what payments any of the 86 physicians might have received to influence their referrals; (3) whether the physicians were referring to Methodist before the affiliation began; or even (4) whether they were employed by or shareholders of West during the period for which claims were gathered. (*Id.* ¶ 203.) He had no factual basis to explain how any alleged kickbacks Methodist paid to West purportedly caused the submission of any of the claims in the dataset reviewed. (*Id.* ¶ 204.) As Mr. Petron conveniently explained: "It's my understanding that their relationship violates the law. And so *all of the claims* are a result of the relationship." (*Id*.) (emphasis added).

This is an astounding and dispositive failure of proof on what the Sixth Circuit recognized in *Martin* as a critical element of AKS liability. The government has not carried its burden to show that any West physician was required to make any referral to Methodist or that any West physician's referral decision was the direct result of some kickback, bribe, or other remuneration paid from Methodist. Indeed, rather than demonstrate but-for causation linking purportedly

unlawful remuneration to any of the West physicians regarding any of their referral decisions, the government speculates that causation *must exist* as to *all claims*. But, "speculation is insufficient to establish a genuine issue of material fact." *Goodman*, 954 F.3d at 865; *see also Jordan*, 987 F.3d at 545; *McQueen*, 782 F. App'x at 466 n.3; *DePalma v. Sec'y of Air Force*, 754 F. App'x 321, 328 (6th Cir. 2018).

The undisputed evidence makes clear that the government's assumption is wrong and the required causation does not exist. Several factors material to the Sixth Circuit's decision in *Martin* are present here, including that (1) neither Methodist nor West mandated referrals to any specific provider, (2) physicians made independent decisions regarding where to refer their patients, and (3) the government fails to establish that any specific referral by any specific West physician would not have otherwise occurred but for some unlawful remuneration. *Martin*, 2023 WL 2661358, at *7–9. Instead, the government engages in precisely the same fallacy the Sixth Circuit rejected in *Martin*; namely, asserting that "nearly anything a [doctor] accepts . . . counts as a *quid*; and nearly anything a [doctor refers] . . . counts as a *quo*." *Id.* at *24. But "that simply is not the law." *Id.*

The West physicians uniformly testified that they were not required to refer to any particular hospital. (SUMF ¶¶ 173–180 (citing Berry Decl. ¶ 16 ("West's participation in the affiliation did not affect my patient referral practices or decisions."); Richey Decl. ¶ 29 ("[M]y choice for patient referrals was never impacted by any payments made from Methodist to West. I was never pressured or instructed by anyone at Methodist or West to refer my patients to a Methodist facility."); Portnoy Decl. ¶ 19 ("I was never pressured or instructed by anyone at Methodist or West to refer my patients to a Methodist facility."); Tillmanns Decl. ¶ 24 ("West's participation in the Affiliation did not affect my patient referral practices or decisions."); Ballo Decl. ¶ 28 ("West's participation in the Affiliation did not alter my patient referral decisions.

Further, my choice for patient referrals was never impacted by any payments made from Methodist to West. I was never pressured or instructed by anyone at Methodist or West to refer my patient to a Methodist facility.")).).[8] All of this testimony is unrebutted.

In fact, it is further undisputed that the West physicians retained privileges and continued to see patients at other facilities. (*See id.* ¶ 178 (citing Somer Dep. 235:12–24 ("Q: Was your decision-making process where to send your patients and what services to order influenced by the fact that West entered into the MSA and PSA with Methodist? A: … the decisions were made based on where we could be assured that our patients got the best care, and if we were confident in the services, that's where we would send them. . . . We never took patients out of another system either. Like, we go where they are in the –and we still do."))) Many of the West physicians used Methodist's facilities prior to the affiliation and have continued to do so after the affiliation agreements expired. (*See id.* ¶ 177 (citing Portnoy Decl. ¶ 19 ("Before the Affiliation, I sent many of my patients to Methodist Germantown Hospital, and I continue to do so today…my choice regarding where to send my patients was never impacted by any payments made from Methodist to West."); Somer Dep. 234:4–12 ("Q: Have you continued to maintain your privileges at

[8] (*See id.* (citing Schwartzberg Dep. 268:9–269:11 ("Q: Did the fact that West was receiving compensation from Methodist under the PSA, MSA, or other agreements, did that impact in any way where you decided to refer patients? A: It did not. Q: Did it impact in any way whether you decided to order certain services or not for patients? A: Had no impact on the services. I tried to order the appropriate services in every case…. Q: Did anyone from Methodist ever instruct you or pressure you to send more patients to Methodist? A: No. Q: Did anyone at Methodist ever instruct you or pressure you to have other West physicians send patients to Methodist? A: No."); Tauer Dep. 249:7–21 ("Q: Did anybody at Methodist ever instruct you or pressure you to send more patients to Methodist? A: No. Q: From what you observed as a leader in the West Clinic practice, did anybody at Methodist ever pressure other West physicians to – on where to send patients or what services to order? A: No. Q: Did Methodist ever condition any of the financial amounts that were paid under any of the agreements on the volume or value of referrals from West? A: No..."); Somer Dep. 235:25–236:2 ("Q: Did anyone at Methodist ever instruct you or pressure you to send more patient to Methodist? A: No.")).).

Methodist? A: Yeah. Q: Do you still use Methodist for services for you patients? A: Yes. Q: How do you decide[] today where to send one of your patients that needs hospital services? A: Wherever they can get they can get the best care.")).)

The undisputed evidence also demonstrates that the West physicians made their referral decisions on a patient-by-patient, service-by-service basis depending upon each physician's considerations of professional judgment, patient choice, physician expertise, where the patient had previously received services, payor requirements, availability of services and specialties, attainment of national accreditations and compliance with national guidelines, and quality. (*Id.* ¶ 178.) These considerations are totally unrelated to any remuneration paid to West, much less remuneration provided to a specific doctor to induce a specific patient referral.

Indeed, the undisputed evidence demonstrates that, to the extent West physicians' referrals to Methodist increased, the increase was due to the higher level of care that had been achieved as a result of the affiliation. (*See id.* (citing Tauer Dep. 249:22–250:11 ("Q: As a result of the affiliation, did you feel like you had more control over the quality of services being provided at Methodist? A: The goal of the program was to make sure that we had more quality in the hospital setting, particularly and in the outpatient setting as we can take advantage of it, so yes, I did. Q: Did that impact your decision or the decisions of other West physicians on where to send patients? A: Given the criteria I gave you earlier about geographic locations and ease for the patient, it certainly did. Q: Quality matters in that respect? A: It always matters."); Richey Decl. ¶¶ 8, 17 ("[A]ffiliation enhanced patient care and outcomes for cancer patients and added to the depth of knowledge and the skillset of practitioners serving the Memphis community….The MSA afforded the West physicians, including myself, the ability to affect patient care at Methodist hospitals in ways that are not otherwise available to individual physicians who were advocating for this type

of specialized treatment. In my opinion, the Affiliation and the MSA allowed the West Cancer Center to provide enhanced care to the Memphis community and to better advocate and support the cancer patient population."); Tillmanns Decl. ¶¶ 25–26 ("When I referred a patient to a Methodist facility, I did so because I believed in my professional opinion that Methodist offered the best care for that patient. . . . I continue to refer my patients to Methodist because I believe it is in the best interest of the patient. . . . I believe that the Affiliation advanced the quality of cancer care in Memphis and created a framework to hold everyone in the community, not just at the West Cancer Center, accountable to one another regarding the quality of care we were providing.")).) These are exactly the types of facts that the Sixth Circuit determined in *Martin* debunk any notion that the conduct at issue violates the AKS.

Because the government has no admissible evidence to support its contention that every single claim submitted during the seven-year affiliation was directly caused by a kickback from Methodist—and, indeed, all the admissible, undisputed evidence regarding the basis for referrals directly contradicts the government's contention—it cannot prove the chain of causation. The failure of proof requires entry of summary judgment.

II. There Is No Evidence that Methodist Violated the AKS.

As a separate ground for summary judgment, the government has not established that Methodist violated the AKS and, thus, cannot establish that Methodist submitted any false certification to Medicare regarding compliance with the AKS. *First*, the government must show, but only speculates, that Methodist paid above fair market value compensation. *Second*, Methodist's certifications of compliance with the AKS were not objectively false.

A. There Is No Evidence of Illegal Remuneration.

The AKS provides for criminal and civil liability for "knowingly and willfully offer[ing] or pay[ing] any *remuneration* (including any kickback, bribe, or rebate) directly or indirectly,

overtly or covertly, in cash or in kind to any person to induce such person ... to refer an individual to a person for the furnishing ... of any item or service" that is reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added).

The AKS itself does not define remuneration, so, in *Bingham*, the Eleventh Circuit looked first to BLACK'S LAW DICTIONARY, which defines "remuneration" in pertinent part as "[p]ayment; compensation." *Id.* at 873. Compensation, in turn, "cannot be given unless some sort of benefit is conferred." *Id.* In light of these definitions, the Eleventh Circuit held that remuneration is provided only when a benefit is conferred and that "the value of a benefit can only be quantified by reference to its fair market value." *Id.* The Eleventh Circuit then looked to the Medicare Act, which defines "remuneration" as "transfers of items or services for free *or for other than* fair market value," 42 U.S.C. § 1320a-7a(i)(6) (emphasis added), and stated that this definition further supported its conclusion that fair market value transactions do not implicate the AKS. *Bingham*, 783 F. App'x at 873-75.[9] Accordingly, the Eleventh Circuit affirmed the district court's grant of summary judgment because the plaintiff did not show that any of the arrangements at issue conferred any benefit *in excess of* fair market value. *Id.* at 874.

Here, the undisputed evidence is that the payments under the parties' agreements were fair market value. Stated conversely, the government, which bears the burden of proof, developed

[9] Although the Sixth Circuit has not directly addressed this issue, it has also held that the word "remuneration" must mean a payment made for other than fair market value. *See Miller*, 648 F. App'x at 561 (quoting statute); *Jones-McNamara*, 630 F. App'x at 400 (same); *see generally Martin,* 20232023 WL 2661358, at (noting that this circuit has assumed twice before that this definition—that remuneration is "items or services for free or for other than fair market value"—applies to the AKS). Further, multiple other courts have construed remuneration to be something other than fair market value. *See, e.g., Bingham v. Baycare Health Sys.*, 2016 WL 8739056, at *5 (M.D. Fla. Dec. 16, 2016); *U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics, Inc*., 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011).

no proof that any payments from Methodist to West were *not* fair market value. Consequently, the parties' conduct did not implicate—and, therefore, could not have violated—the AKS.

The government takes the remarkable position in a motion in limine that whether payments Methodist made to West were "fair market value" is irrelevant because Methodist has not raised any "safe harbor" defense. (*See* Dkt. No. 307.)[10] But, the Eleventh Circuit in *Bingham* concluded that "the issue of fair market value is not limited to" a defendant's safe harbor defense, "but is rather something [plaintiff] must address in order to show that [the defendant] offered or paid remuneration." *Bingham*, 783 F. App'x at 873. The Eleventh Circuit affirmed the district court's grant of summary judgment because the relator did not show that any of the arrangements conferred any benefit in excess of fair market value. *Id.* at 874. In sum, compensation paid is not unlawful remuneration if the compensation was fair market value for services rendered.[11]

1. The Undisputed Evidence Demonstrates that Methodist's Payments to West Were Fair Market Value.

Because the government does not consider fair market value to be relevant to establish a

[10] The U.S. Department of Health and Human Services ("HHS") has issued various safe harbor regulations that protect individuals and entities from prosecution and sanctions under the AKS if they satisfy the safe harbor's conditions. Compliance with a safe harbor is *voluntary*, and the government has made clear that failure to comply with a safe harbor does not mean that an arrangement is *per se* illegal. *See, e.g.,* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. at 77861 (Dec. 2, 2020) ("[W]e emphasize that safe harbors are voluntary and that any assessment of liability under the Federal anti-kickback statute requires an analysis of the facts and circumstances specific to the arrangement, including the intent of the parties.").

[11] Whether a payment was fair market value is critical to the assessment of whether an arrangement contains appropriate safeguards as well as relevant to the parties' intent. 85 Fed. Reg. at 77685. Thus, the fair market value nature of a payment is not, and can never be, "irrelevant" to an AKS analysis. Evaluating whether a payment is fair market value is critical to determining whether an arrangement implicates the AKS, whether an arrangement includes appropriate safeguards, and whether the parties have the requisite intent to violate the statute.

violation of the AKS, it chose not to develop affirmative proof regarding the fair market value nature of the compensation paid in this case. As a result, the only evidence in the record demonstrates that Methodist paid fair market value under the agreements with West. Furthermore, the government developed no proof that any individual West physician received any compensation that was not fair market value for that physician's services.

The undisputed evidence in this case is that payments were at fair market value. The government disclosed two expert witnesses, Tim Smith and Lucy Carter, who both expressly disclaimed conducting any fair market value review of the compensation arrangements in this case. (SUMF ¶ 211.)[12] Conversely, Methodist's fair market value expert Todd Mello conducted a comprehensive fair market review of the compensation paid to West under the PSA and concluded that whether viewed under any valuation approach–market, cost, or income–the payments made to West were within fair market value. (*Id.* ¶¶ 46, 212.) Indeed, Mr. Mello found that in viewing aggregate compensation across the term of the PSA, West Clinic *earned less* under the PSA than it had been earning in independent practice prior to the affiliation. (*Id.* ¶ 47.) Similarly, Mr. Mello found that the payments made under the MSA fell within fair market value. (*Id.*) Additionally, even taking into account any alleged "errors" in the contemporaneous valuations asserted by the government's expert, Mr. Mello concluded that the amount of payments still fell within fair market value. (*Id.*)

Witnesses testified that the parties set compensation in the agreements at amounts that qualified industry experts determined to be fair market value. (*Id.* ¶¶ 38–40 (citing Richey Decl. ¶ 18 ("I was also involved in discussions relating to the re-evaluations of the management and

[12] The government may have conducted no fair market value review of any of the arrangements because it knows that such reviews, such as that conducted by Methodist's expert, would only further validate that fair market value was paid.

professional services agreements. I understood that Methodist's payment of professional and management fees was subject to fair-market value opinions. I always expected and understood that West would be paid fair market value for the management and professional services provided by the West physicians")))); (*see also id.* ¶ 38 (citing McLean Dep. Vol. I 260:4–6 ("Methodist agreed to pay under the [MSA] based on the fair market value opinion that we received."), 22:2–5 ("We agreed to pay, under the [PSA], fair market value rates determined by an outside fair market value appraiser."); McLean Dep. Vol. II 147:18–21 ("[T]he only thing we paid [West] was . . . a PSA, an MSA, and an [APA], and they were all based on the final fair market value opinions that we got[.]")).)

For its part, West did not expect compensation differences among the parties responding to its RFP because the compensation would be determined by outside fair market value opinions. (*Id.* ¶ 23.) Compensation discussions "revolved around fair market value, always." (*Id.* ¶ 38 (quoting Shorb Dep. 88:15–16).) The parties set compensation under the agreements based on the fair market value opinions, and then negotiated within those ranges. (*Id.* ¶¶ 41–42.)

In obtaining fair market value reviews, the parties never limited the questions the fair market valuators could ask and supplied all information the evaluators requested. (*Id.* ¶ 43.) Once the relevant information was provided, the parties expected that the valuators would use the information to calculate a range of fair market values. (*Id.* ¶ 44.) The parties would then rely upon the experts' opinions. (*Id.* ¶ 41 (quoting Mounce Dep. 605:24–606:14 ("I relied on all the third parties including the valuators. Altegra, Pinnacle, and HAI in their evaluations that were put forward.")).) Methodist believed that compensation paid by Methodist to West under each of the Affiliation Agreements was fair market value and that all of the Affiliation Agreements complied with the law. (*Id.* ¶ 45.)

Finally, even if the government attempted to show that Methodist provided above fair market value payments to West Clinic (which it cannot), the government has offered no proof connecting payments from Methodist to any individual West physician, much less to *every* West physician such that all claims related to West were false. West had over 70 physicians with varying roles and varying dates of employment who performed varying work. The government offers no proof as to how West compensated individual physicians, whether West compensated employed or contracted physicians differently from shareholder physicians, or whether and how West passed on any allegedly improper payments received from Methodist to any physician. At this stage in the litigation, simply speculating that individual doctors received remuneration from Methodist is not sufficient to constitute proof of remuneration with respect to that physician.

2. The Factual Record Demonstrates that the Government's Contentions in its Complaint and Interrogatories Are Unsupported by Evidence.

The government offers no evidence to establish unlawful remuneration as a matter of law for any of its contentions in its Complaint or Interrogatory responses:

First, regarding the allegation that West operated at sites without reimbursing Methodist, the undisputed evidence demonstrates that the parties developed a contemporaneous methodology to ensure that Methodist received adequate compensation. (SUMF ¶¶ 60–61 (citing McLean Dep. Vol II 8:18–22 (stating he "did an exhaustive review of all the cost centers, what was in the cost centers, and identified these cost centers as ones where there should be costs that . . . have some joint activities of which I should be charging for")).) In fact, during the course of the affiliation, West paid Methodist approximately $8.2 million to cover costs associated with West operations that did not benefit Methodist. (*Id.* ¶ 62.) The government has not determined that $8.2 million was outside fair market value, nor has it determined what it believes fair market value for those costs *should have been.* (*Id.* ¶ 211.) And, as the government conceded, it does not actually require

parties to have any fair market value opinion, (*id.* ¶ 209), nor does it specify how fair market value should be determined when calculating overhead costs or anything else, (*id.* ¶ 210). Therefore, Methodist is entitled to summary judgment. *See U.S. ex rel. McDonough v. Symphony Diagnostic Serv., Inc.,* 36 F. Supp. 3d 773, 781 (S.D. Ohio 2014) (granting summary judgment to defendant where Relator failed to show that his cost approach was required under the AKS or to provide a reliable "comparison point" from which an inference could be drawn that the defendant's cost analysis was "'so low' that it violated the AKS").

Second, as to the contention that payments to West for clinical services exceeded the collections for those services, there is no evidence that payments exceeding collections violates the AKS. In the only fair market value review of the PSA, and hence in the only undisputed evidence, Mr. Mello validated the uniform contemporaneous views of the witnesses that payments *were* at fair market value. (SUMF ¶¶ 46–47, 212.) And, although the government carries the burden, it has offered no evidence of its own regarding the fair market value for the physicians' services. (*Id.* ¶ 211.) Moreover, the Magistrate Judge deemed it admitted that the government has not identified any rules, regulations, guidance, official publications, provider education materials, or reports that forbid payment to a physician in an amount greater than his or her professional collections. (Dkt. No. 312); (*see also* SUMF ¶ 214.)

Third, as to payments under the MSA, the evidence is undisputed that payments that Methodist made to West fell within the permitted range of fair market value, (SUMF ¶¶ 49, 212), and through the work of the West physicians, the service line was able to develop treatment pathways protocols for treating various cancer types; increase compliance with standardized care plans and protocols; increase documentation within patient records; increase communication with other providers; improve patient satisfaction scores; improve staff feedback scores; reduce hospital

admissions; reduce emergency department visits and admissions; reduce surgical-site infections; reduce central-line infections; reduce post-op infections; open an acute care clinic; create patient-navigation program; create a survivorship program; create a genetics program; increase genetic testing; increase molecular testing; increase clinical trials; and improve cancer survival outcomes for breast, lung, uterine, and colon cancers. (*See id.* ¶¶ 154–172.)

Fourth, the LEA was paid at cost (*id.* ¶ 56), and the government does not submit evidence that any payments made under the MSA were not at fair market value as provided in contemporaneous reports. Again, although the government bears the burden of proof, it cannot offer any evidence regarding what it believes to be fair market value for the leased employees, much less any explanation for how Methodist's at-cost payment for those leased employees exceeded fair market value—under either the LEA or the MSA.

Because payments made under the agreements were at fair market value, there is no remuneration under the AKS. *See Bingham*, 783 F. App'x at 870-73; *U.S. ex rel. Jamison v. McKesson Corp.,* 900 F. Supp. 2d 683, 699 (N.D. Miss. 2012) (finding that "[i]n the context of the AKS, courts use 'fair market value' as the gauge of value when assessing the remuneration element of the offense" and when fair market value was paid, government could not prove AKS violation); *see also Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006) (noting that "[r]elators cannot prove that the Hospital Defendants received remuneration—something of value—without comparing the contracted rates with fair market value" and, when relators could not establish any value other than fair market value was paid, dismissing relators' claim at summary judgment). If no remuneration is paid, there cannot be a violation of the AKS.

B. The Government Has Not Established that Methodist Made Any Objectively False Certification.

The government contends that Methodist knowingly made false certifications on claims

and cost reports that it was complying with the AKS, when, in fact all claims submitted associated with the affiliation resulted from AKS violations. (Compl. ¶¶ 39–77, 354.) For Methodist's certifications to be false under the FCA, they must be "objectively false" because a "statement may be deemed 'false' for purposes of the False Claims Act only if the statement represents an 'objective falsehood.'" *U.S. ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) (citations omitted); *see also U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014); *U.S. ex rel. Wilson v. Kellogg Brown & Root*, 525 F.3d 370, 377-78 (4th Cir. 2008).

The government cannot establish that Methodist's certifications were objectively false where the only fair market valuation conducted regarding the main components of the affiliation found the payments to be within fair market value. The government's Complaint and Interrogatory responses at most merely posit differing opinions as to fair market value. For example, did Methodist's methodology for calculating West's allocation of overhead costs over-compensate or under-compensate West? Were Methodist's payments under the PSA and MSA too high or too low, given that there is no government-prescribed methodology for determining fair market value in the first instance? When all that exists, at most, is a difference of opinion whether payments were set at fair market value, there is no objective falsity and no FCA violation. *See generally U.S. ex rel. Bell v. Cross*, 2021 WL 5544685, at *2 (11th Cir. Nov. 26, 2021); *United States v. AseraCare, Inc*., 938 F.3d 1278, 1297 (11th Cir. 2019). Because here there is no objective falsity, but rather a difference of opinion, there is no FCA violation as a matter of law. *See Thomas*, 593 F. App'x at 143; *U.S. ex rel. Hill v. Univ. of Med. & Dentistry of New Jersey*, 448 F. App'x 314, 316 (3d Cir. 2011); *Yannacopoulos*, 652 F.3d at 836; *Kellogg Brown & Root*, 525 F.3d at 377–78; *U.S. ex rel. Morton v. A Plus Benefits, Inc*, 139 Fed. Appx. 980, 982 (10th Cir. 2005).

III. There Is No Evidence That Methodist Engaged in Knowing or Willful Conduct in Violation of the AKS or FCA.

Aside from there being no proof of remuneration, no proof linking unlawful remuneration to a specific West referring physician, and no proof of objective falsity, there is also no proof of any "knowing and willful" attempt to violate the AKS. A corporate defendant "can only act ***and know*** through its officers." *United States v. Carter*, 311 F.2d 934, 941–43 (6th Cir. 1963) (emphasis added).[13] Here, the government has failed to show that Methodist, through any authorized employee,[14] knowingly and willfully violated the AKS for at least two reasons.

First, it is well-established that defendants cannot knowingly submit false claims when they act within a reasonable interpretation of what is, at most, an ambiguous law and when there is no official governmental guidance, such as a court of appeals decision or binding agency determination, that would warn defendants away from their reasonable interpretation. *See, e.g., Olhausen*, 2022 WL 1203023, at *2 (because defendant had an "objectively reasonable interpretation" of applicable requirements, plaintiff could not show defendant had the requisite intent to violate the FCA).[15]

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[13] Courts in the Sixth Circuit and beyond have consistently rejected the notion that a company can be held liable under the FCA based on the collective knowledge of employees, meaning that the government must be able to pinpoint a specific individual with the requisite scienter. *See United States v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 567–68 (E.D. Tenn. 2014) (discussing widespread rejection of "collective knowledge" theory in FCA cases that would allow proof of scienter based on piecing together "innocent" knowledge held by multiple corporate officials); *see also, e.g., Consol. Med. Transp.*, 458 F. Supp. 2d at 680 ("Relators have not set forth any evidence concerning the state of mind or intent of any of the relevant agents of the Hospital Defendants.").

[14] Although earlier versions of the complaint included former Methodist CEO Gary Shorb and former CFO Chris McLean as named defendants, the government dropped them as defendants when it intervened. (*Compare* Dkt Nos. 59, 169 *with* Dkt. No. 235.)

[15] *See also U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 343044 (4th Cir.), *reh'g en banc granted*, 2022 WL 1467710 (4th Cir. May 10, 2022), *and opinion vacated on reh'g en banc*, 49 F.4th 873 (4th Cir. 2022) ("Because [Defendant's] reading of the Rebate Statute was at the very least objectively reasonable and because it was not warned away from that reading by authoritative

Methodist could not act with the requisite scienter to violate the AKS because it had a reasonable interpretation of the law—that under the Medicare Act's definition of "remuneration", payments set at fair market value do not constitute unlawful remuneration under the AKS.[16] That is, where Methodist believed it was paying West fair market value compensation for West's services, Methodist did not knowingly and willfully pay West any bribes or kickbacks.

During discovery, the government did not identify any court of appeals decision or binding agency determination that transactions at fair market value could constitute AKS violations. Indeed, the Eleventh Circuit has stated the opposite: that Medicare law provides that a fair market value transaction **cannot** constitute unlawful remuneration in violation of the AKS. *Bingham*, 783

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guidance, it did not act 'knowingly' under the False Claims Act.); *United States v. Supervalu Inc*., 9 F.4th 455, 472 (7th Cir. 2021), *cert. granted sub nom*. *U.S. ex rel. Schutte v. SuperValu Inc*., 143 S. Ct. 644 (2023) ("Because [defendant] had an objectively reasonable understanding of the regulatory definition … and no authoritative guidance placed it on notice of its error, the relators have not shown that [defendant] acted knowingly."); *United States v. Allergan, Inc*., 746 F. App'x 101, 109-10 (3d Cir. 2018) (plaintiff failed to plead FCA claims where defendants had a reasonable interpretation of an ambiguous statute and relator did not plead that government had published any official guidance that would "warn" defendants away from their reasonable interpretation); *United States ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551, 552 (9th Cir. 2017) (finding that scienter under the FCA could not be established because defendant's good faith interpretation of regulation was reasonable); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016) (affirming dismissal because defendant had a reasonable interpretation of ambiguous rule and because there had not been sufficient "official government warning" to warn defendant away from its reasonable interpretation); *U.S. ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 289 (D.C. Cir. 2015) (holding that the FCA imposes no liability for the reasonable interpretation of an ambiguous regulation in the absence of interpretive guidance "that might have warned [the defendant] away from the view it took") (citation omitted); *U.S. ex rel. Ketroser v. Mayo Found*., 729 F.3d 825, 832 (8th Cir. 2013) (holding that defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA").

[16] In FCA actions, official governmental guidance must be from an appellate court decision or a binding agency pronouncement. *See, e.g., U.S. ex rel. Complin v. N.C. Baptist Hosp.*, 818 F. App'x 179, 182-84 n.6 (4th Cir. 2020); *United States v. Safeway Inc*., 466 F. Supp. 3d 912, 931, 939-41 (C.D. Ill. 2020), *aff'd*, 30 F.4th 649 (7th Cir. 2022).

F. App'x at 873–75. Hence, even if the court were to find that Methodist's interpretation—that fair market value transactions do not violate the AKS—is incorrect, circuit courts uniformly recognize that a reasonable interpretation of an ambiguous standard shows that Methodist could not have acted with the requisite intent. *See, e.g., Olhausen*, 2022 WL 1203023, at 2; *Safeway, Inc.,* 30 F.4th 649; *SuperValu Inc.,* 9 F.4th at 472; *Allergan, Inc.*, 746 F. App'x at 109-10.[17]

Second, independent of Methodist's reasonable interpretation of the AKS, the government cannot establish an AKS violation because it cannot satisfy the AKS's knowing and willful standard. To establish that defendants knowingly and willfully paid remuneration to induce referrals, the government must establish that defendants knew that their conduct was wrongful. *See, e.g., United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998); *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996); *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989).[18]

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[17] The government admitted in this case that it has never defined a particular method to assess fair market value. (SUMF ¶ 214.) Nor has the government ever issued official governmental guidance warning any health care provider from utilizing a market approach as its fair market value methodology. *See, e.g.,* Dkt. No. 312. Thus, until Congress enacts a statute or the agency enacts a regulation prohibiting the industry from using a market approach, Methodist cannot have possessed the requisite scienter to violate the AKS by reasonably relying on an expert's viewpoint that the projected revenue of a service line can be used as a proxy for the level of management service that would be necessary to manage that service line. *See N.C. Baptist Hosp.*, 818 F. App'x at 182-84 n.6; *Safeway Inc.*, 466 F. Supp. 3d at 939-41.

[18] Because the alleged predicate violation in this FCA action involves a breach of the AKS, a criminal statute, the government must demonstrate a violation of that statute beyond a reasonable doubt. *See, e.g., McKesson*, 900 F. Supp. 2d at 698 n.7 (noting in ruling against government at trial in FCA action alleging a violation of the AKS that it applied preponderance standard rather than the criminal intent standard of "beyond a reasonable doubt" because the government's case was not close, but noting "that if this case were a closer call, the proper course would likely be to use criminal intent" beyond a reasonable doubt standard to prove the underlying AKS violation) (citation omitted); *but see Cairns*, 42 F.4th at 834.

A defendant does not violate the AKS by merely desiring to obtain referrals from a business arrangement that is designed for other legitimate purposes. *See, e.g., U.S. ex rel. Ruscher v. Omnicare, Inc.,* 663 F. App'x 368, 374 (5th Cir. 2016); *see also McKesson*, 900 F. Supp. 2d at 698–99 (noting that when "analyzing alleged violations of the AKS, a key distinction is that the law . . . it criminalizes knowing and willful acceptance of remuneration in return for such referrals" and that "in order to violate the AKS, it is not enough to covet the business of another, there must actually be some bad intent to violate the law" and rejecting the government's AKS allegation because it "presented no proof that either party did anything illegal or in bad faith").

Courts have identified multiple factors that indicate when defendants do not act with unlawful intent. For example, where defendants operate in good faith, participate in common industry practices, and engage in actions consistent with legitimate business purposes, they do not violate the AKS.[19] *See U.S. ex rel. Kosenske v. Carlisle HMA,* 2010 WL 1390661, at *10 (M.D. Pa., Mar. 31, 2010); *McDonnell v. Cardiothoracic & Vascular Surg. Assocs*., 2004 WL 3733402, at *9 (S.D. Ohio, Jul. 28, 2004) *aff'd*, 165 F. App'x 423 (6th Cir. 2006); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1401 (9th Cir. 1995); *Consol. Med. Transp*., 458 F. Supp. 2d at 675–77, 683–84.

The record evidence is overwhelming that Methodist operated at all times in good faith. It engaged qualified industry experts to structure the deal. (SUMF ¶¶ 28-31.) It engaged (although not required by the government) independent valuation firms to value the various components of

[19] Likewise, under the FCA, courts routinely rule that defendants do not act with reckless disregard or deliberate ignorance when they rely upon experts as Methodist did here continuously. *See, e.g*., *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.,* 495 F.3d 103, 107–110 (3d Cir. 2007); *U.S. ex rel. Folliard v. Govplace,* 930 F. Supp. 2d 123, 137 (D.D.C. 2013), *aff'd,* 764 F.3d 19 (D.C. Cir. 2014); *U.S. ex rel. Crenshaw v. DeGayner*, 622 F. Supp. 2d 1258, 1278 (M.D. Fla. 2008); *U.S. ex rel. Ervin v. Hamilton Secs. Grp.*, 298 F. Supp. 2d 91, 101–02 (D.D.C. 2004).

the transaction. (*Id*. ¶¶ 51, 65, 71, 76, 143, 146.) It maintained documentation of the payments to West as well as the reimbursements it sought from West for non-affiliation expenses. (*See id*. ¶¶ 61-62.) It communicated constantly with West to ensure the legitimate goals of the affiliation were being met or exceeded, and it kept voluminous records of the work West performed and the accomplishments it achieved during the affiliation. (*See id.*) [20]

After more than six years of investigation and litigation, the best the government has to offer is its expert's opinion that Methodist, as a health system, *should have known* the valuation opinions it obtained during its affiliation were unreliable based on inferences the government's expert drew from his valuation expertise, overlooked footnotes in the opinions, and the benefit of hindsight. Merely identifying supposed "errors" or "inconsistencies" in valuations or in compliance with the minutiae of contracts over the course of years does not establish a knowing violation of the AKS or FCA. *See U.S. ex rel. Owens v. First Kuwaiti*, 612 F.3d 724, 734 (4th Cir. 2010). The government has not set forth any evidence concerning the state of mind or intent of any of the relevant agents of Methodist that would establish that any agent individually or collectively were knowing and willful participants in any unlawful conduct.

[20] During discovery, Methodist sought 30(b)(6) testimony from the government regarding its contention that there was "no evidence to show what exactly West did, let alone specifically who provided management services." (SUMF ¶ 205.) The government's designee first acknowledged that the government had issued no laws or regulations requiring that time records or any proof of services to comply with the AKS. (*Id.* ¶ 206.) Furthermore, he acknowledged that despite being designated to testify about the government's contention that there was "no evidence to show what exactly West did," he had had not been provided and had not reviewed voluminous documents produced in the litigation evidencing services provided, such as minutes of meetings of the CPQ Committee, the Commission on Cancer, the Clinical Leaders Council, and the Education Committee; nor did he have any knowledge of what work West did to achieve various accreditations for the cancer center; or whether West had performed various services such as standardizing admission and discharge protocols, recruiting surgical oncologists and transplant physicians, standardizing surgical equipment tools, or reduced ED visits. (*Id.* ¶ 207.) His testimony was representative of the government's case as a whole: broad assertions but no supporting facts.

CONCLUSION

The United States cannot establish multiple elements of its case, including: (1) that any claims "resulted from" a violation of the AKS (causation), (2) that Methodist paid West above fair market value for services rendered (falsity), or (3) that Methodist knowingly and willfully violated the AKS and knowingly submitted false claims in violation of the FCA (scienter). Because a failure of proof on any one of these elements mandates entry of summary judgment, Methodist requests that the Court dismiss all claims in the United States' Complaint in Intervention with prejudice, and enter judgment in favor of Defendants.

Dated: April 14, 2023.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served on the following counsel via the Court's CM/ECF email notification system on this the 14th day of April, 2023:

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